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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,386	03/19/2004	Michael L. Garrison	1000-036	7250

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EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
11/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,386	GARRISON ET AL.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,11,12,15-17 and 19-21* is/are pending in the application.

4a) Of the above claim(s) *5-7,15-17 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 06/30/2009.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-2, 4, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gillick et al.** (U.S. Patent No. **6,383,206**) in view of **Keegan et al.** (U.S. Patent No. **7,144,408**).

Claims 1-2: Gillick et al. disclose a method for delivering and deploying an expandable intraluminal device **72**, providing a delivery system comprising an elongate member **30** having proximal and distal ends and defining a lumen, the delivery system further comprising an ancillary delivery device **64** at least partially disposed in the lumen and having a means for spacing **66** a portion of the elongate member from a wall surface of a body vessel, and the expandable intraluminal medical device **72** circumferentially disposed about a portion of the elongate member (Figures 8-10), wherein the expandable medical device **72** is disposed about the interior of the elongate member **70** in Figure 8 and is disposed around the exterior of the elongate member in Figure 11. A

guidewire **35** is placed in the body vessel and the elongate member is advanced over the guidewire, which is removed from the body vessel by retracting the guidewire through the lumen of the elongate member. The ancillary delivery device is inserted into the proximal end of the elongate member and advancing the ancillary delivery device through the lumen until the means for spacing exits the distal end of the elongate member. It is noted that the elongate member **30** may be advanced or retracted relative to the ancillary delivery device **64** or vice versa in order to expand the means for spacing. The distal end of the elongate member is inserted into a body vessel **14**, and the distal end of the elongate member is advanced through the body vessel to the desired point of treatment (Figure 8). A portion of the elongate member is spaced from a wall surface of the blood vessel at a point distal to said expandable intraluminal medical device **72** by activating the means for spacing **66** such that an axial portion of the elongate member disposed between a proximal end of the means for spacing and a distal end of the intraluminal medical device is free of contact with the wall surface of the body vessel (Figure 9), wherein spacing a portion of the elongate member includes the expandable intraluminal device, and the expandable intraluminal medical device is deployed from the elongate member while the elongate member has been spaced from a wall surface of the body surface, again by the means for spacing **66**, wherein the deploying step and the spacing step are performed at the same time (Figure 10). Lastly, the elongate member is withdrawn from the body vessel (col. 9, lines 12-14).

Gillick et al. do not disclose retracting the means for spacing into the lumen of the elongate member while maintaining the position of the distal end of the elongate member relative to the deployed expandable intraluminal medical device.

In Figures 51-53 Keegan et al. teach retracting a means **301** for spacing into a lumen of an elongate member **325** while maintaining the position of a distal end of the elongate member relative to a deployed expandable intraluminal medical device **321**. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the elongate member **30** and the means for spacing **66** of Gillick et al. by allowing the means for spacing to be retracted into a lumen of the elongate member while maintaining the position of the distal end of the elongate member, as taught by Keegan et al., in order to maintain a low profile of the means for spacing for removal from the body vessel.

Claim 4: Gillick et al. disclose the means for spacing **66** comprising a basket formed from at least two wire members and having expanded and collapsed configurations (Figures 8-11).

Claims 8 and 11: Gillick et al. disclose the delivery system further comprises a sheath **70** circumferentially disposed about the elongate member and movable along the elongate member, and wherein the step of deploying the expandable intraluminal medical device comprises retracting the sheath from a position about the expandable intraluminal medical device and the activating the means for spacing also includes retracting the sheath from a position about the means for spacing (Figures 9-10; col. 9, lines 1-7).

3. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gillick et al.** (U.S. Patent No. **6,383,206**) in view of **Keegan et al.** (U.S. Patent No. **7,144,408**)., as applied to claim 1 above, and further in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**)

Claim 12: Gillick et al. and Keegan et al. disclose the claimed steps except for the expandable intraluminal medical device comprising a venous valve.

Pavcnik et al. teach an intraluminal venous valve **43** that is deployed within a blood vessel and exerts force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6, page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to the combined invention of Gillick et al. and Keegan et al., since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device for a therapeutic procedure, such as a prosthetic venous valve.

Response to Arguments

4. Applicant's arguments with respect to claims 1, 2, 4, 8, and 11-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734